

EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII)

USE

EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII) is used to treat pain that is painful enough to need this type of medicine throughout the entire day in people who have been regularly taking similar pain medicines. EXALGO is an opioid (narcotic). It has risks of addiction, abuse, misuse, overdose, and death, even when taken at the dose your doctor prescribed. Because of this, EXALGO should be used only when other medicines don't work. EXALGO is not used as an as-needed pain reliever.

IMPORTANT RISK INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING BREATHING PROBLEMS; ACCIDENTAL USE; WITHDRAWAL SYNDROME IN NEWBORNS

Addiction, Abuse, and Misuse

Addiction, abuse, and misuse of EXALGO can lead to overdose and death.

Life-threatening Breathing Problems

EXALGO can cause severe breathing problems that can kill you. Crushing, chewing, or dissolving EXALGO can cause you to get too much medicine, which can kill you.

Accidental Use

Taking EXALGO by mistake can cause overdose and death, especially in children.

Withdrawal Syndrome in Newborns

Taking EXALGO while pregnant can cause withdrawal in your newborn baby. It may kill them if they are not treated.

DO NOT USE EXALGO IF:

- You were not previously taking another opioid (narcotic) pain medicine
- You have severe asthma or other breathing problems.
- You have a bowel blockage.
- You have had previous surgeries or disease that caused your stomach or bowels to become narrower
- You are allergic to hydromorphone, sulfites, or any other ingredient.

WARNINGS

- EXALGO is a controlled substance. It has risks of abuse, misuse, and addiction like other opioid medicines used for pain. Crushing, chewing, snorting, or injecting EXALGO can cause overdose and death. Injecting the inactive ingredients in EXALGO can damage your heart, which can kill you. Drug abuse by injection can also cause the spread of diseases such as hepatitis and HIV (AIDS).
- EXALGO can cause severe breathing problems that can kill you, even when it is used as your doctor prescribed. The risk of severe breathing problems is highest when you first start taking EXALGO or when your dose is increased. People who are elderly or who already have severe breathing problems have a higher chance of having severe breathing problems when they take EXALGO.
- Low blood pressure, excessive sedation, severe breathing problems, and death can occur if you take EXALGO with certain other medicines. These include drugs to treat anxiety or help you sleep, similar pain medicines, or alcohol.
- The use of EXALGO could result in low blood pressure.
- EXALGO may complicate head injuries.
- EXALGO may aggravate seizures in people who experience seizures.
- Do not abruptly stop taking EXALGO.
- EXALGO could affect your ability to drive a car, use machinery, or do other dangerous tasks.

SIDE EFFECTS

- Serious side effects include severe breathing problems which can kill you, overdose, and death.
- The most common side effects are constipation, nausea, vomiting, drowsiness, headache, fatigue/lack of strength, and dizziness.

USE IN CERTAIN POPULATIONS

- Babies born to mothers who use opioids like EXALGO could have trouble breathing and symptoms of withdrawal.
- EXALGO passes into breast milk. It may harm your baby if you breastfeed.
- EXALGO is not approved for children.